UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UFCW LOCAL 1500 WELFARE FUND, on behalf of itself and all those similarly situated,

Plaintiff,

vs.

JAZZ PHARMACEUTICALS IRELAND LIMITED, JAZZ PHARMACEUTICALS, INC., ROXANE LABORATORIES, INC., HIKMA PHARMACEUTICALS PLC, EUROHEALTH (USA), INC., and WEST-WARD PHARMACEUTICALS CORP.,

Defendants.

Case No. _____

Jury Trial Demanded

CLASS ACTION COMPLAINT

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Plaintiff UFCW Local 1500 Welfare Fund brings this class action against Defendants Jazz Pharmaceuticals Ireland Limited, Jazz Pharmaceuticals, Inc. (together, "Jazz"), Roxane Laboratories, Inc., Hikma Pharmaceuticals PLC, Eurohealth (USA), Inc., and West-Ward Pharmaceuticals Corp. (together, "Roxane"), for claims under the Sherman Act and various state laws to recover damages and injunctive relief for the substantial injuries it and others similarly situated have sustained arising from Defendants' anticompetitive conduct. Plaintiff's allegations are based on personal knowledge as to Plaintiff, and Plaintiff's own actions and upon information and belief as to all other matters.

NATURE OF THE ACTION

1. This action arises from an unlawful scheme between Jazz and Roxane to delay the entry of generic competition for Jazz's blockbuster medication Xyrem®. Xyrem (sodium oxybate oral solution) is indicated to treat two common symptoms associated with narcolepsy: excessive daytime sleepiness and cataplexy.

2. Developed by Orphan Medical, the FDA approved Xyrem for the treatment of cataplexy in 2002. In 2005, Jazz acquired Xyrem, when it purchased Orphan Medical. That year, the FDA also approved Xyrem for use in treating excessive daytime sleepiness.

3. Xyrem is an "orphan drug," treating fewer than 200,000 Americans per year. However, despite the relatively small patient pool, Xyrem has become a commercial success, generating billions of dollars in sales for Jazz since its acquisition. While Xyrem only cost $2.04 per 1-milliliter dose in 2007, by 2014, it cost $19.40 per 1-milliliter dose. By year-end 2019, Xyrem sales have comprised over three-quarters of Jazz's revenues.

4. With expiration of Jazz's orphan drug exclusivity over Xyrem nearing, several generic manufacturers, including Roxane, Amneal Pharmaceuticals, Lupin Pharmaceuticals, and Par Pharmaceutical, filed Abbreviated New Drug Applications ("ANDAs") seeking FDA

approval of their competing generic versions of Xyrem. Competition from these generics likely would have driven down the price of Xyrem by upwards of 90%, saving drug purchasers, including Plaintiff and the Classes, billions of dollars.

5. In 2010, Roxane filed the first ANDA seeking approval of generic Xyrem. Roxane's ANDA contained certain certifications claiming that the patents purportedly covering Xyrem—known as Paragraph IV certifications—were invalid, unenforceable, or not infringed by Roxane's proposed generic Xyrem. As the first generic competitor to file an ANDA for generic Xyrem, Roxane was entitled to 180 days of generic marketing exclusivity—meaning that upon FDA approval of its generic Xyrem ANDA, Roxane would be the only generic version of Xyrem permitted on the market for 180 days (with the exception of an authorized generic ("AG") licensed by Jazz). Upon the expiration of the 180-day exclusivity period, any other approved generic manufacturer could begin marketing its generic Xyrem, leading to increased price competition.

6. However, to stymie the ability of Roxane—and other generics—to market less expensive generic versions of Xyrem, Jazz embarked on a pattern of anticompetitive behavior to slow down and ultimately eliminate the competitive threat they posed. ***First***, to protect its cash cow, Jazz filed serial and abusive patent infringement lawsuits—*nine* patent infringement lawsuits against Roxane alone, covering over a dozen patents. Many of these patents were improperly listed in the Orange Book or were obtained through inequitable conduct before the Patent and Trademark Office ("PTO"). Several of these patents were later invalidated by the Patent Trial and Appeal Board ("PTAB") and Federal Circuit. The practical effect of Jazz's conduct was to delay resolution of patent litigation, causing the Roxane patent infringement litigation, which began in 2010, to persist for nearly seven years.

7. ***Second***, Jazz abused regulatory processes concerning the development of a single shared system ("SSS") for a Risk Evaluation and Mitigation Strategy ("REMS")—a drug safety program the FDA requires drug manufacturers to develop when a particular drug has a potential for misuse or abuse—covering Xyrem and its generic equivalents. Although Section 505-1 of the Food, Drug, and Cosmetic Act ("FDCA") requires that brand drugs and their generic equivalents use an SSS for REMS, Jazz stonewalled, obfuscated, and took contradictory positions during its REMS negotiations with the FDA and the would-be generic competitors. While transitioning from a predecessor risk management program to a REMS for Xyrem, Jazz requested that the FDA remove the requirement to distribute Xyrem through a single pharmacy company as part of the risk management program. Jazz claimed that the removal of the single-pharmacy requirement would "increase patient access without compromising patient safety" and that the requirement "imposes numerous impediments to patient access to Xyrem, possibly depriving narcolepsy patients of an important medication . . . and potentially affect[ing] their lives dramatically."[1] The FDA agreed, stating that the final REMS "should not contain the single pharmacy limitation."[2]

8. However, after generic competitors filed ANDAs for generic Xyrem and sought to negotiate an SSS REMS with Jazz, Jazz abruptly changed its position. When the FDA informed Jazz it was requiring a "modification to the REMS under the Agency's statutory authority, which . . . would remove the single pharmacy limitation" Jazz filed "a formal dispute resolution request, appealing the Division of Neurology Product's REMS modification notification and claiming that the Agency's '*assertion that the closed-loop distribution system for Xyrem is no longer necessary is not only unsupported, it puts patients and others at risk.*'"[3]

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[1] Xyrem REMS Waiver Ltr. at 6.

[2] *Id.* at 6 (emphasis in original).

[3] *Id.* at 7 (emphasis added).

Jazz's change in position was not made for any legitimate reason—it was simply to frustrate and prolong negotiations on the SSS and in turn, delay approval of any Xyrem ANDA. And it worked.

9. Although the FDA ultimately granted Roxane and other generics a waiver from the SSS requirement in January 2017, the waiver came after *four years* of unsuccessful negotiations with Jazz. These prolonged negotiations also caused the FDA to delay the approval of Roxane's ANDA, which was approved the same day as the SSS waiver. Thus, in the words of the FDA, the delay may have "***impose[d] a substantial cost to the U.S. healthcare system, as Xyrem remained, until now, shielded from generic competition***."[4]

10. ***Third***, in January 2017, the FDA granted final approval of Roxane's ANDA and therefore was in a position to launch its generic Xyrem during the pendency of the patent litigation. In April 2017, as the patent trial on the Xyrem patents approached—placing Jazz's monopoly at significant risk—Jazz settled its patent infringement claims against Roxane through an unlawful reverse payment to Roxane. Under the patent settlement, Jazz provided Roxane with a license to sell an authorized generic ("AG") version of Xyrem beginning January 1, 2023, with an option to extend the license for five years. Notably, though, the deal also contained a promise by Jazz not to launch its own AG of Xyrem to compete against Roxane's AG for as long as Roxane continued to license the AG from Jazz (the "no-AG agreement"), providing Roxane with a significant and valuable inducement in exchange for delaying its launch for nearly six years.

11. Because Jazz's launch of an AG would have cut Roxane's sales during 180-day marketing exclusivity by between 40% and 50% over that 180-day period, Jazz's "no-AG" promise conferred significant monetary value—worth hundreds of millions of dollars—to

[4] *Id.* at 16 n.49 (emphasis added).

Roxane. This payment in exchange for Roxane's agreement to delay its competitive entry well exceeded any litigation costs saved by Jazz or Roxane through settlement and thus constitutes a large reverse payment under *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

12. To remedy past and ongoing injury to Plaintiff and members of the Classes (defined below), Plaintiff brings this action on behalf of itself and all others similarly situated to restrain Defendants' anticompetitive conduct and restore competition to the sodium oxybate marketplace. Plaintiff also seeks damages under state law to compensate it and all others similarly situated who have overpaid, and will continue to overpay, for Xyrem.

THE PARTIES

A. Plaintiff

13. Plaintiff UFCW Local 1500 Welfare Fund ("Local 1500") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York 11590. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with 15,000 members, is the largest grocery union in New York. During the Class Period (as defined below), Local 1500 indirectly purchased, paid, or reimbursed for some or all of the purchase price for Xyrem. Local 1500 made such payments and/or reimbursements for members located in New York. Local 1500 paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct and, accordingly, suffered injury to its business and property.

B. Defendants

14. Jazz Pharmaceuticals Ireland Limited ("Jazz Ireland") is a pharmaceutical developer and manufacturer with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin, 4, Ireland. Jazz Ireland is a signatory to the patent settlement agreement with Roxane (defined below) that Plaintiff challenges in this litigation.

15. Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals") is a pharmaceutical manufacturer with its principal place of business at 3180 Porter Drive, Palo Alto, California 94304. Jazz Pharmaceuticals is a signatory to the patent settlement agreement with Roxane (defined below) that Plaintiff challenges in this litigation.

16. Jazz Pharmaceuticals Ireland Limited and Jazz Pharmaceuticals, Inc. are collectively referred to as "**Jazz**". During the Class Period, Jazz marketed and sold Xyrem in the United States.

17. Roxane Laboratories, Inc. ("Roxane Laboratories") is a generic pharmaceutical manufacturer with its principal place of business at 2001 Arlington Lane, Columbus, Ohio 43212. Roxane Laboratories is a signatory to the patent settlement agreement with Jazz Plaintiff challenges in this litigation.

18. Hikma Pharmaceuticals PLC ("Hikma") is a pharmaceutical manufacturer with its principal place of business at 1 New Burlington Place, London, W1S 2HR, United Kingdom. Hikma is a signatory to the patent settlement agreement with Jazz Plaintiff challenges in this litigation.

19. Eurohealth (USA), Inc. ("Eurohealth") is a pharmaceutical manufacturing company with its principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. Eurohealth is a signatory to the patent settlement agreement with Jazz Plaintiff challenges in this litigation.

20. West-Ward Pharmaceuticals Corp. ("West-Ward") is a generic pharmaceutical manufacturer with its principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. West-Ward is a signatory to the patent settlement agreement with Jazz Plaintiff challenges in this litigation.

21. Roxane Laboratories, Inc., Hikma Pharmaceuticals PLC, Eurohealth (USA), Inc., and West-Ward Pharmaceuticals Corp. are collectively referred to as "**Roxane**."

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 16 of the Clayton Act, 15 U.S.C. § 26, because this action arises under the federal antitrust laws. This Court also has subject matter jurisdiction under 28 U.S.C. § 1332(d) and 28 U.S.C. § 1367.

23. Venue is appropriate within this district under 15 U.S.C. § 15(a), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. § 1391(b) (general venue provision). Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

24. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

REGULATORY FRAMEWORK

25. Generic competition allows purchasers at all levels of the pharmaceutical chain of distribution to purchase generic drugs at prices lower than those drugs' brand counterparts. Generic competition to a single brand drug can provide potentially billions of dollars in savings

to consumers, pharmacies, and other drug purchasers, as well as to private health insurers or state Medicaid programs, both of which reimburse the cost of drug purchases by covered individuals.

26. The FDA sets the standards for the approval of generic drugs. Upon satisfaction of FDA regulations governing, among other things, safety, efficacy, and labeling, the FDA confers upon a generic drug a therapeutic equivalence rating from AA to BX. Typically an "A" (*i.e.*, AA, AB, AN, AO, AP, AT) rated generic is assigned, "those for which there are no known or suspected bioequivalence problems or for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence."[5] As defined in the regulations, bioequivalence is:

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.[6]

27. The A rating permits the generic drug to be substituted for the brand drug at a pharmacy counter. All States permit—and indeed, some States require—pharmacists to substitute an A-rated generic drug for the corresponding brand drug, unless the prescribing healthcare provider has specifically stated that the brand drug is to be used.

28. Many health insurers and other third-party payors have adopted policies to encourage the substitution of A-rated generic drugs for their brand name counterparts. For example, many third-party payors implement a tiering system that places certain drugs on different benefit tiers. A drug that is placed on one tier may receive only partial reimbursement, while a drug placed on another tier may receive full reimbursement. Typically, branded drugs are

[5] Orange Book Preface (38th ed.), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.

[6] 21 C.F.R. § 320.1(e).

placed on a different tier than their corresponding generic. Furthermore, branded drugs with a generic equivalent are usually subject to smaller reimbursements or higher co-pays, while generic drugs will be given total (or near total) reimbursement with a limited, or no, co-pay.

29. As a result of these policies, healthcare professionals are incentivized to prescribe generics so that they can receive higher reimbursements. In addition, these policies also incentivize end users to request generic drugs because of the cost savings they may receive with respect to their co-pay.

30. Because both healthcare professionals and end-users are economically incentivized to prefer generic drugs, A-rated generics are usually able to capture a substantial portion of the market.

31. The first A-rated generic is typically priced at a discount to its brand counterpart. As additional A-rated generics obtain FDA approval to enter the market, the resulting increase in competition causes prices of both the first generic and the brand counterpart to drop dramatically.

32. Empirical studies show that within a year of generic entry, generics will have obtained about 90% of the market, *i.e.*, pharmacists fill 90 of every 100 prescriptions for the compound with an A-rated generic. Indeed, an FTC study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[7]

A. FDA New Drug Approval Process

33. The Federal Food, Drug and Cosmetic Act (the "FDCA") and its accompanying regulations set the standards for the approval of any new drug compound that is to be marketed,

[7] FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), available at http://emmanuelcombe.org/delay.pdf.

sold, or distributed in the United States. Drug manufacturers seeking to gain FDA approval for a new drug must file a New Drug Application ("NDA"). Applicants filing an NDA are required to provide a host of information demonstrating the safety and efficacy of their drug, including, but not limited to: (1) information and studies regarding the chemistry of the drug substance, which includes information concerning how the drug is manufactured; (2) information and studies regarding nonclinical pharmacology and toxicology for the new drug; (3) information and studies regarding the human pharmacokinetics and bioavailability; and (4) information and data from clinical studies on human subjects.[8]

34. Upon satisfying FDA regulations concerning efficacy, safety and labeling, the FDA will approve the NDA, permitting the applicant to market, sell, and distribute the approved drug to the U.S. public.

35. In addition, upon receiving FDA approval, the brand manufacturer will list any patents it believes cover the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is more commonly referred to as the "Orange Book."[9]

36. However, only drug substance patents (active ingredient), drug product patents (formulation and composition), and method-of-use patents qualify for listing in the Orange Book.[10] Thus, for example, process patents covering a new drug are not eligible for listing (although they may be asserted in a future patent litigation against any allegedly infringing product).

[8] *See* 21 C.F.R. § 314.50(c)-(d).

[9] 21 U.S.C. § 355(j)(7)(A)(iii).

[10] 21 C.F.R. § 314.53(b).

37. In listing patents in the Orange Book, the FDA acts in a ministerial capacity. It does not verify whether the patents listed in the Orange Book are properly listed but instead relies on the accuracy and truthfulness of the NDA applicant.

38. In addition to the protection conferred by patents covering the brand manufacturer's drug, NDA applicants are afforded additional statutory protections for a drug containing a new active ingredient. NDAs for drugs containing a new active ingredient are given up to five years of marketing exclusivity before any generic drug manufacturer may file an application for the approval of a generic formulation.[11]

B. The Hatch-Waxman Act Encourages and Facilitates Generic Drug Approvals

39. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the "Hatch-Waxman Act."

40. The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and highly costly NDA, the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an ANDA.

41. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug NDA it references concerning, among other things, safety and efficacy.[12] The ability to rely on the scientific data published in the referenced NDA obviates the need for duplicative and expensive experimentation and clinical trials, which in some instances can result in out-of-pocket

[11] 21 U.S.C. § 355(j)(5)(F)(ii).

[12] 21 U.S.C. § 355(j)(2)(A).

costs of upwards of $130 million. The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.[13] In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

42. Although the Hatch-Waxman Act seeks to facilitate generic competition, the brand manufacturer retains the right to enforce any patents associated with its brand drug. As part of its ANDA, the applicant must certify that the generic drug will not infringe any of the Orange Book patents because: (1) no patents exist on the brand drug; (2) the patents have expired; (3) the patents will expire by the time the generic product comes to market; or (4) the patents are invalid, unenforceable, or will not be infringed by the sale of the generic product.[14] When a generic drug manufacturer certifies that the patents covering the referenced brand drug are invalid, unenforceable, or will not be infringed, it known as a "Paragraph IV certification."

43. When a generic drug manufacturer files a Paragraph IV certification asserting that one or more patents listed in the Orange Book are invalid, unenforceable or will not be infringed, it must serve notice of its certification to both the brand manufacturer and the owner(s) of the patent.

44. The issuance of a Paragraph IV certification creates an "artificial act" of patent infringement, permitting the patent owner to file a patent infringement suit against the ANDA applicant making the Paragraph IV certification(s).[15]

[13] 21 U.S.C. § 355(j)(4).

[14] 21 U.S.C. § 335(j)(2)(A)(vii)(I)–(IV).

[15] 35 U.S.C. § 271(e)(2)(A).

45. If the brand manufacturer files a patent infringement suit against the ANDA applicant within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) 30 months, running from the date the when the Paragraph IV notice was served on the patentee; or (b) a court ruling that the patent is invalid, unenforceable, or not infringed by the ANDA.[16] During the 30-month stay, the FDA may grant "tentative approval" of an ANDA if the FDA determines that the ANDA would otherwise qualify for final approval but for the 30-month stay.

46. Despite the threat of a patent infringement suit and a 30-month stay, the Hatch-Waxman Act creates powerful incentives for generic drug manufacturers to file ANDAs. Specifically, the Hatch-Waxman Act grants a 180-day period of market exclusivity to the first applicant (the "first filer") to file a substantially complete ANDA containing a Paragraph IV certification.

47. During the 180-day period of market exclusivity, the first filer only competes against the brand manufacturer and potentially any AG marketed under the brand manufacturer's NDA; all other generic ANDA applicants must wait until either the expiration of the 180-day exclusivity period or a court order finding that each of the patents that are the subject of a Paragraph IV certification are invalid, unenforceable, or not infringed.

48. Because all other ANDA generics are barred from the market during the first filer's 180-day exclusivity period, the first-filing ANDA applicant is able to price its generic version at a price that is around 20%-30% below the brand drug's price. This allows the first filer to gain market share, while simultaneously taking advantage of the price umbrella created by the

[16] 21 U.S.C. § 355(j)(5)(B)(iii).

brand manufacturer's pricing. Indeed, during the first-filer's 180-day exclusivity period, the first-filer can capture over 80% of branded and generic unit and dollar sales.

49. However, once the first filer's 180-day exclusivity period expires, all other FDA-approved ANDA filers can begin to market their generic equivalents, driving down prices substantially and reducing the profitability of both the branded drug and the first filer's generic.

C. Brand Manufacturers and First Filers Can Manipulate the Regulatory Structure to Delay the Emergence of Generic Competition

50. Because the Hatch-Waxman Act automatically stays the approval of an ANDA when a brand manufacturer files an infringement suit against an ANDA applicant, brand manufacturers have an incentive to liberally (and sometimes wrongfully) list in the Orange Book all patents potentially covering the brand drug. Upon a generic drug manufacturer's filing of an ANDA with a Paragraph IV certification, the brand manufacturer will then sue on one or more of those Orange Book patents to trigger the stay.

51. Frequently, patent infringement suits arising from Paragraph IV certifications result in settlements. In some of these settlements, the brand manufacturer will offer the generic drug manufacturer some form of consideration (*i.e.*, payment) in exchange for the generic drug manufacturer agreeing to delay entry of its generic product. These settlements commonly are referred to as "pay-for-delay agreements."

52. These pay-for-delay agreements have the practical effect of permitting the settling brand manufacturer to retain a significant portion of its monopoly profits while only ceding a relatively small portion of those profits to the settling generic drug manufacturer in exchange for the generic drug manufacturer's agreement to delay market entry.

53. The incentive to create these types of agreements is particularly acute between a brand manufacturer and the first-filing ANDA applicant. In these agreements, the brand

manufacturer seeks to delay generic entry and preserve its monopoly for as long as possible. Typically, a generic drug manufacturer will want as early an entry date as possible, if only for the higher present value of earlier sales.

54. However, unlike other generic drug manufacturers, a first-filing ANDA applicant has the potential benefit of 180 days of marketing exclusivity where it can reap substantial revenues as potentially one of two products in the relevant drug market. A first-filing ANDA applicant's continued litigation against the brand manufacturer runs the risk that the court will find the patent(s) at issue valid, enforceable, and/or infringed by the first filer's ANDA. A finding of validity, enforceability, and/or infringement by a court would negate the first filer's Paragraph IV certification and disqualify that generic drug manufacturer from receiving the benefit of 180 days of marketing exclusivity. Thus, the first filer has an acute interest in settling the patent infringement lawsuit as a means of guaranteeing its 180-day exclusivity period, and, in turn, the economic bounty associated with it.

55. With the promise of substantial revenue during its generic exclusivity period secure, the first filer cares little about date of ultimate launch sought by the brand manufacturer—that is so long as the brand name manufacturer sufficiently compensates the first filer for the delay in launching its generic.

56. Moreover, brand manufacturers are willing to pay substantial sums to the first filer for any delay in generic launch in exchange for the promise that the first filer will not enter before a certain date. This is because the value of monopoly profits is so great that the brand manufacturer is willing to pay more to ensure the first filer's acquiescence to the later launch date. The generic drug manufacturer's acquiescence to a later entry date, in turn, preserves a

substantial portion of the brand manufacturer's monopoly profits in the period prior to the first filer's agreed-to launch date.

57. In essence, by settling with the brand manufacturer, the first filer receives a double bonus in the form of: (1) a substantial payment from the brand manufacturer to forgo early entry; and (2) the guarantee of substantial revenues as the only generic on the market (absent an authorized generic) during that first filer's 180-day exclusivity period. Under such circumstances, the first-filing ANDA applicant has limited incentive to continue the patent litigation for purposes of securing a judgment of non-infringement, invalidity, or unenforceability—and thus, a potentially earlier entry date—because it still retains the economic bounty associated with its statutory 180-day exclusivity period.

58. Such pay-for-delay agreements also create powerful disincentives for subsequent ANDA filers to continue defending their ANDAs in patent infringement litigations against the brand manufacturer. Specifically, once it becomes apparent that the brand manufacturer and the first filer have settled their patent litigation, subsequent ANDA filers usually will not pursue litigation aggressively, and, often times, settle as well.

59. Subsequent ANDA filers are unlikely to continue litigating because obtaining a judgment that the patents subject to Paragraph IV certifications are invalid, unenforceable, or not infringed provides little pay-off to them. For example, prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066, a judgment of patent invalidity or unenforceability would not cause the first filer to lose its 180-day exclusivity period; rather, the subsequent filer's success in litigation would only accelerate the start of the first filer's exclusivity period. The subsequent ANDA filer must still wait until the first filer's 180-day exclusivity period expires, and only at that point can

other FDA-approved ANDA applicants enter the market as well. Thus, these pay-for-delay agreements effectively "park" exclusivity and cause a bottleneck in the timing of full generic entry.

60. More recent legislation has not alleviated the problems caused by pay-for-delay agreements. MMA attempts to make the incentives underlying pay-for-delay agreements less attractive by enumerating a series of forfeiture events that, if triggered, will deprive a first filer of its 180-day exclusivity period.

61. One of the key forfeiture events under the MMA is if the first filer fails to obtain tentative approval within 30 months of submitting its ANDA.[17]

62. While noble in purpose, scholars have found the MMA's "use it or lose it" provision to be woefully inadequate in deterring anticompetitive agreements to delay generic competition for two reasons. First, market acceleration clauses, which are standard components of pay-for-delay agreements, allows the first filer to accelerate its entry into the market ahead of the later date agreed to with the brand manufacturer in its settlement should a subsequent generic challenger prevail in the courts.

63. Second, brand manufacturers can avoid triggering a potential forfeiture event by only suing on some, but not all, of the patents subject to the first filer's Paragraph IV certifications. Because a subsequent filer needs to obtain a judgment of invalidity or non-infringement with respect to *all* patents that are the subject of a first filer's Paragraph IV certification in order to trigger the forfeiture event, the brand manufacturer need only sue on a few of the patents to avoid that scenario.

[17] 21 U.S.C. § 505(j)(5)(D)(i)(I).

64. The lengthy and expensive nature of patent litigation makes it such that subsequent filing generic drug manufacturers typically do not have the stomach to pursue litigation to the end. Indeed, by the time a generic drug manufacturer secures the judgments necessary, "the clock [will] simply run[] out on the subsequent generic filers fighting to open the market earlier than the date agreed to by the first filer in its 'parked' exclusivity settlement."[18]

D. No-Authorized Generic Agreements

65. Pay-for-delay agreements can be augmented by including terms in which the brand manufacturer agrees not to launch an authorized generic to compete with the first filer during its 180-day exclusivity period.

66. As a threshold matter, a first filer's 180-day exclusivity period does not prevent a brand manufacturer from marketing its own authorized generic during that period of generic exclusivity. Authorized generics are chemically identical to the branded drug and are marketed under the brand manufacturer's NDA. An authorized generic can be marketed either through a generic drug division of the brand manufacturer or through a third-party generic drug manufacturer.

67. Competition from an authorized generic during the first filer's 180-day exclusivity period substantially reduces the first filer's profit margins and increases price competition that ultimately benefits consumers and other purchasers of the branded drug and the first filer's generic equivalent.

68. In a 2011 study titled, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (the "FTC 2011 Report"), the FTC found that authorized generics capture a

[18] Letter from Michael Carrier, Rutgers School of Law, to Sen. Tom Harkin, at 3 (Apr. 21, 2011), *available at* http://www.hpm.com/pdf/blog/LIPITOR%20-%20Balto-Carrier%20Ltr.pdf.

significant number of generic drug sales, reducing the first filer's revenues by 40–52 percent on average during the 180-day exclusivity period.

69. Although first filers make significantly less money when they are forced to compete with an authorized generic during the first 180 days, consumers benefit from the lower prices caused by competition between the authorized generic and the first filer.

70. In light of the substantial negative effects on a first filer's bottom-line that can be caused by the presence of an authorized generic, a promise by a brand manufacturer to not launch, or license, an authorized generic confers significant monetary value to a first filer. The value conferred to a first filer is tantamount to a payment for agreeing to delay generic entry and competition.

E. REMS Abuse

1. REMS Background

71. For certain drugs, which pose potential risks of abuse or misuse, the FDA may require drug manufacturers to submit for approval a Risk Evaluation Mitigation Strategy ("REMS"). The Food & Drug Administration Amendments Act ("FDAAA") added Section 505-1 to the FDCA. It defines REMS as a "required risk management plans that use risk minimization strategies beyond . . . professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks."[19] Examples of REMS include education addressing possible risks associated with use of particular drugs, certification and training of prescribers and pharmacists, developing protocols for tracking distribution and dispensing of particular drugs down the distribution chain.

[19] 21 U.S.C. § 355-1.

72. Certain REMS include protocols known as Elements to Assure Safe Use ("ETASU"), which control distribution of a particular drug and may include prescriber certification requirements, pharmacies or dispensaries certifications, restricted distribution to specific settings (*e.g.*, hospitals), patient monitoring, and enrollment of patients to registries.

73. When a generic manufacturer files an ANDA for a drug encumbered by a REMS, the FDCA requires that the brand and generic manufacturers work together to develop a Single Shared System ("SSS") for REMS.[20] The FDA may waive the requirement to develop an SSS under two circumstances. The first circumstance is when the burden of creating an SSS outweighs the benefits.[21] The second is when an aspect of the ETASU is "claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection."[22]

74. However, FDA waivers are by and large the exception. FDA officials have stated that their "[e]xpectation is [the] successful formation of SSS."[23]

2. REMS Abuse

75. Although REMS are intended to ensure patient safety, brand manufacturers have used REMS as a pretext for refusing to provide samples to generic manufacturers seeking to use those samples for purposes of establishing their product's bioequivalence to the branded product.

76. In other instances, despite statutory commands requiring cooperation in developing an SSS and FDA statements strongly encouraging the development of an SSS, branded manufacturers have used the development of REMS as a mechanism for delaying

[20] 21 U.S.C. § 355-1(i)(1)(B).

[21] 21 U.S.C. § 355-1(i)(1)(B)(i).

[22] 21 U.S.C. § 355-1(i)(1)(B)(ii).

[23] Elaine Lippmann, Risk Evaluation and Mitigation Strategies (REMS), at 33, https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM563789.pdf.

generic entry. For example, brand manufacturers have stonewalled and frustrated generic manufacturers in the development of an SSS by taking inconsistent positions or engaging in other dilatory tactics during negotiations.

77. In still other instances, brand manufacturers encumber their ETASU with patents of questionable validity and strength. Often these patents simply describe a process for distributing and monitoring the sale and use of a drug. They do not describe a compound or method of using a drug and thus cannot be listed in the Orange Book. Yet, in many instances, these REMS patents are improperly listed in the Orange Book. Because generic manufacturers are required to make certifications against all Orange Book patents—even those listed improperly—improper listing of REMS patents provides the brand manufacturer the opportunity to sue on these patents, along with any other patents covering the drug, or a method of using a drug. As a result, generic manufacturers must incur increased litigation expense and delay in resolving issues surrounding these patents.

78. According to one study published in 2014, the estimated cost of REMS abuse to the U.S. healthcare system is $5.4 billion annually.

FACTUAL BACKGROUND ON XYREM

79. Orphan Medical Inc. ("Orphan Medical") developed Xyrem and, on October 2, 2000, filed with the FDA NDA 21-196. On July 17, 2002, the FDA approved Xyrem for the treatment of cataplexy associated with narcolepsy. Because Xyrem active ingredient sodium oxybate is a controlled substance (Schedule C-III), in conjunction with the approval of the NDA, the FDA also approved a Risk Management Program ("RiskMAP") for Xyrem.

80. The Xyrem RiskMAP required:

(a) "Implementation of a restricted distribution program for Xyrem;"

(b) "Implementation of a program to educate physicians and patients about the risks and benefits of Xyrem;"

(c) "Filing of the initial prescription only after the prescriber and patient have received and read the educational materials;" and

(d) "Maintenance of a registry of all patients and record of all prescribers."[24]

81. As part of the risk management program, the FDA also required the distribution of a Medication Guide for patients informing them of important safety information when taking Xyrem.[25]

82. In April 2005, Jazz acquired Orphan Medical, including the rights to Xyrem, for $122.6 million. Three years later, on November 18, 2005, the FDA approved a new indication for Xyrem: treatment of excessive daytime sleepiness in patients with narcolepsy.

83. On August 29, 2008, Jazz submitted a REMS proposal.

84. The FDA ultimately approved Jazz's proposed REMS for Xyrem on February 27, 2015. The Xyrem REMS includes the following requirements, among others: (1) healthcare provider certification; (2) enrollment of Xyrem patients into "Patient Enrollment" plan; and (3) pharmacy certification.

85. Jazz also obtained several patents concerning its proposed REMS for Xyrem. Specifically, Jazz obtained the following seven patents covering the Xyrem REMS (the "Xyrem REMS Patents"):

(a) U.S. Patent No. 7,668,730 ("the '730 patent");

(b) U.S. Patent No. 7,765,106 ("the '106 patent");

[24] July 17, 2002 Xyrem FDA Approval Ltr. at 2.

[25] *Id.*

(c) U.S. Patent No. 7,765,107 ("the '107 patent");

(d) U.S. Patent No. 7,895,059 ("the '059 patent");

(e) U.S. Patent No. 8,457,988 ("the '988 patent");

(f) U.S. Patent No. 8,589,182 ("the '182 patent"); and

(g) U.S. Patent No. 8,731,963 ("the '963 patent")

86. Each of these patents was listed in the Orange Book as seen below:

Patent and Exclusivity for: N021196

Product 001
SODIUM OXYBATE (XYREM) SOLUTION 500MG/ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	6780889	07/04/2020		DP			
001	7262219	07/04/2020		DP			
001	7668730	06/16/2024			U-1110		
001	7765106	06/16/2024			U-1069		
001	7765107	06/16/2024			U-1070		
001	7851506	12/22/2019			U-1101 U-1102		
001	7895059	12/17/2022			U-1110		
001	8263650	12/22/2019		DP	U-1101 U-1102		09/20/2012
001	8324275	12/22/2019			U-1101 U-1102		12/05/2012
001	8457988	12/17/2022			U-1110		07/02/2013
001	8589182	12/17/2022			U-1110		
001	8731963	12/17/2022			U-1110		05/30/2014
001	8772306	03/15/2033			U-1532		07/09/2014
001	8859619	12/22/2019		DP			10/28/2014
001	8952062	12/22/2019			U-1101 U-1102		02/19/2015
001	9050302	03/15/2033			U-1532		07/08/2015
001	9486426	03/15/2033			U-1532		12/06/2016
001	9539330	12/22/2019		DP			02/08/2017

87. However, as explained below, the Xyrem REMS Patents were: (1) improperly listed in the Orange Book because they did not claim the Xyrem drug compound or an approved method of using Xyrem; and (2) invalid for reasons of obviousness in light of prior art.

DEFENDANTS' UNLAWFUL CONDUCT

88. Jazz undertook a prolonged campaign against would-be generic manufacturers of Xyrem. As part of its campaign, Jazz: (1) engaged in a pattern of serial, abusive patent prosecution and litigation and (2) abused the REMS regulatory process.

A. Jazz's Serial and Abusive Patent Prosecutions and Infringement Litigation

89. Jazz's pattern of abusive patent litigation against generic manufacturers delayed the resolution of any legitimate patent dispute. Jazz sought to protect its monopoly over Xyrem through a series of petitions to the PTO to obtain patents purportedly covering Xyrem, and then listing those patents in the Orange Book, forcing Roxane and other generics to submit successive Paragraph IV certifications on those newly listed patents, triggering successive 30-month stays and delays on the FDA's ability to approve pending ANDAs for generic Xyrem.

90. Some of Jazz's more egregious patent-related behavior included (1) using information obtained in pending patent litigation in proceedings before the PTO to obtain additional patent coverage as a means of "trapping" generics into an infringement, (2) failing to disclose material prior art references in the prosecution of certain patents, and (3) asserting the Xyrem REMS Patents and other patents against generic rivals, despite their improper listing in the Orange Book.

1. Roxane I

91. On or about October 14, 2010 Roxane notified Jazz that it had submitted ANDA No. 202090, seeking to market a generic version of Xyrem, and that its ANDA included a Paragraph IV certification as to the '889, '219, '730, '106, and '107 patents, claiming that each was invalid, unenforceable, or not infringed by Roxane's ANDA product.

92. On November 22, 2010, Jazz sued Roxane in the District of New Jersey, Case No. 2:10-cv-06108. Jazz alleged that Roxane's ANDA infringed the '889, '219, '730, '106, and '107

patents. Under the Hatch-Waxman Act, Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

93. Roxane pleaded numerous affirmative defenses and counterclaimed. Roxane sought declaratory judgments that the '889, '219, '730, '106, and '107 patents were invalid, unenforceable, and/or not infringed by Roxane's ANDA product. Roxane also sought orders requiring removal of the '730, '106, and '107 patents (each a Xyrem REMS Patent) from the Orange Book because those patents were improperly listed in the Orange book due to the fact that they neither covered the Xyrem drug compound nor a method of using Xyrem.

2. Roxane II

94. On or about January 10, 2011, Roxane notified Jazz that it had submitted a Paragraph IV certification as to the '506 patents, claiming it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

95. On February 4, 2011, Jazz sued Roxane in the District of New Jersey, Case No. 2:11-cv-00660. Jazz alleged that Roxane's ANDA infringed the '431 and '506 patents. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

96. Roxane pleaded numerous affirmative defenses and counterclaimed. Roxane sought declaratory judgments that the '431 and '506 patents were invalid, unenforceable, and/or not infringed by Roxane's ANDA product. Roxane also sought an order requiring removal of the '506 patent from the Orange Book because the '506 patent was improperly listed in the Orange Book due to the fact that it did not claim an approved indication for Xyrem or a method of using Xyrem.

97. On April 6, 2011, *Roxane II* was consolidated with *Roxane I*.

3. Roxane III

98. On or about March 22, 2011, Roxane notified Jazz that it had submitted a Paragraph IV certification as to the '059 patent, claiming that it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

99. On May 2, 2011, Jazz sued Roxane in the District of New Jersey, Case No. 2:11-cv-02523. Jazz alleged that Roxane's ANDA infringed the '059 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

100. Roxane pleaded numerous affirmative defenses and counterclaimed. Roxane sought a declaratory judgment that the '059 patent was invalid, unenforceable, and/or not infringed by Roxane's ANDA product. Roxane also sought an order requiring removal of the '059 patent from the FDA's Orange Book because the patent was improperly listed in the Orange book. The '059 patent does not claim an approved indication or any method of using Xyrem.

101. On June 15, 2011, *Roxane III* was consolidated with *Roxane I*.

4. Roxane IV

102. On or about October 5, 2012 Roxane notified Jazz that it had submitted a Paragraph IV certification as to the '650 patent, claiming it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

103. On October 26, 2012, Jazz sued Roxane in the District of New Jersey, Case No. 2:12-cv-06761. Jazz alleged that Roxane's ANDA infringed the '650 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

104. Roxane pleaded numerous affirmative defenses and counterclaimed. Roxane sought a declaratory judgment that the '650 patent was invalid, unenforceable, and/or not

infringed. Among other things, Roxane alleged that the patents were unenforceable because Jazz had engaged in inequitable conduct during the prosecution of the '650 patent, including the withholding of material prior art reference (Chem Abstract ES302338).

105. Roxane, in fact, had disclosed this prior art reference to Jazz as part of Roxane's Initial Invalidity Contentions regarding the '431 patent family (of which the '650 patent is a member) in Civil Action No. 2:10-cv-6108. Yet, despite its duty to disclose material prior art references to the PTO,[26] Jazz did not disclose this prior art reference in connection with the prosecution of the application that would later issue as the '650 patent.[27] Jazz, in fact, admitted that it did not disclose Chem Abstract ES302338 in the prosecution of the '650 patent.[28]

106. On April 12, 2013, *Roxane IV* was consolidated with *Roxane I*.

107. On December 30, 2013, the Court permitted Roxane to amend its answers and counterclaims to include allegations in support of prosecution laches and unclean hands.[29] The Court held that Roxane had plausibly alleged facts to support to such claims.[30]

5. <u>Roxane V</u>

108. On December 4, 2012, PTO issued the '275 patent to Jazz. The claims of the '275 patent cover methods of use and administration of sodium oxybate.

109. The very next day, on December 5, 2012, Jazz sued Roxane in the District of New Jersey, Case No. 2:12-cv-07459. Jazz alleged that Roxane's ANDA infringed the '275 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

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[26] *See* 37 C.F.R. § 1.56.

[27] Case No. 2:12-cv-06761, ECF No. 5 ¶¶ 25–26.

[28] Case No. 2:10-cv-6108, ECF No. 293, ¶ 22.

[29] Case No. 2:10-cv-6108, ECF No. 283.

[30] Case No. 2:10-cv-6108, ECF No. 282.

110. Roxane answered and pleaded numerous affirmative defenses, including non-infringement and invalidity.

111. On April 12, 2013, *Roxane V* was consolidated with *Roxane I*.

6. Roxane VI

112. On or about January 15, 2015, Roxane notified Jazz that it had submitted a Paragraph IV certification as to the ’306 and ’619 patents, claiming that they were invalid, unenforceable, or not infringed by Roxane’s ANDA product.

113. On February 20, 2015, Jazz sued Roxane in the District of New Jersey, Case No. 2:15-cv-01360. Jazz alleged that Roxane’s ANDA infringed the ’203, ’306, and ’619 patents. Jazz’s filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA’s ability to approve Roxane’s ANDA.

114. Roxane answered, pleaded numerous affirmative defenses, and counterclaimed. Roxane sought a declaratory judgment that the ’203, ’306, and ’619 patents were invalid and/or unenforceable and that Jazz’s claims of infringement were barred by both prosecution and litigation laches and the unclean hands doctrine.

115. Specifically, Roxane claimed that Jazz “unreasonably and inexcusably delay[ed] the presentation of claims” covered by the ’203 and ’619 patents.[31] Both patents are part of the ’431 patent family and both issued from patent applications that were filed *over a decade* after the patent application that issued as the ’431 patent.[32]

116. With respect to both Roxane alleged that

> Jazz has embarked on an abusive course of conduct in which it gleans information about Roxane’s non-infringement positions, then runs to the Patent Office to obtain new, patent-counsel

[31] Case No. 2:15-cv-01360, ECF No. 12, ¶¶ 3, 56.

[32] *Id.* at ¶¶ 26, 77.

> invented patent claims by filing continuation applications of patent applications filed ten plus years ago, and then files in seriatim law suits against Roxane based on these unreasonably presented patent claims, to delay resolution of patent infringement actions against Roxane's ANDA No. 202090.[33]

117. In the case of both the '203 and '619 patents, Roxane accused Jazz of filing patent applications that would later issue as the '203 and '619 patents *after* obtaining information about Roxane's ANDA product and Roxane's invalidity non-infringement contentions relating to the patent-in-suit in the *Roxane I* litigation.[34]

118. Roxane alleged that Jazz delayed filing the patent applications that would later issue as the '203 and '619 patents in order to

> seek additional claims to cover Roxane's sodium oxybate product or to circumvent Roxane's non-infringement defenses to the claims of the original patents-in-suit and has improperly kept and unreasonably delayed in keeping patent applications pending, not to claim additional inventions the inventors believed they had invented, but to glean information from Roxane to craft broader or different claims in an attempt to read on Roxane's sodium oxybate product.[35]

119. Roxane also moved to dismiss Jazz's infringement claims as to the '306 patent, arguing that the patent did not claim patent-eligible subject matter.[36] The court administratively terminated the motion and stayed discovery on the '306 patent pending the outcome of a pending *inter partes* review on the '306 patent.[37]

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[33] *Id.* at ¶ 22.

[34] *Id.* at ¶¶ 64, 66, 75

[35] *Id.* at ¶ 27 (the '203 patent). *See also id.* at ¶ 78 (the '619 patent).

[36] Case No. 2:15-cv-01360, ECF No. 10-1.

[37] Case No. 2:15-cv-01360, ECF No. 34. The Patent Trial and Appeal Board ultimately declined to institute an *inter partes* review for the '306 patent. *See Amneal Pharms. LLC v. Jazz Pharms. Ireland Ltd.*, 2016 WL 5222883 (PTAB July 28, 2016).

7. Roxane VII

120. On or about April 16, 2015, Roxane notified Jazz that it had submitted a Paragraph IV certification as to the '062 patent, claiming that it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

121. On June 1, 2015, Jazz sued Roxane in the District of New Jersey, Case No. 2:15-cv-03684. Jazz alleged that Roxane's ANDA infringed the '062 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay on the FDA's ability to approve Roxane's ANDA.

122. Roxane asserted affirmative defenses and counterclaims. Roxane sought a declaratory judgment of non-infringement and invalidity.

123. In addition, Roxane pleaded that Jazz's claims of infringement were barred by laches. Roxane alleged that Jazz had a history of abusive conduct, using information gleaned from the litigation positions Roxane took in ongoing patent litigation and then running to the PTO "to obtain new, patent-counsel-invented patent claims by filing continuation applications of patent applications filed ten plus years ago, and then fil[ing] *in seriatim* lawsuits against Roxane based on these unreasonably presented patent claims in order to delay resolution of patent infringement actions against Roxane's ANDA . . . ."[38]

124. Roxane further alleged that

> Jazz improperly delayed filing the '437 Application [the application that issued as the '062 patent] to seek additional claims to cover Roxane's sodium oxybate product or to circumvent Roxane's non-infringement defenses to the claims of the original patents-in-suit and has improperly kept and unreasonably delayed in keeping patent applications pending, not to claim additional inventions the inventors believed they had invented, but to glean information from Roxane to craft broader or different claims in an attempt to read on Roxane's sodium oxybate product.

[38] 2:15-cv-03684, ECF No. 7, ¶ 43.

* * * *

> Jazz has used newly-issued patents to try to serially consolidate new patent lawsuits against Roxane with older patent lawsuits against Roxane – all regarding Roxane's ANDA No. 202090 – in order to delay resolution of these patent infringement litigations relating to Roxane's sodium oxybate ANDA product.[39]

125. On November 23, 2015, *Roxane VII* was consolidated with *Roxane VI*.

8. Roxane VIII

126. On or about December 14, 2015, Roxane notified Jazz that it had submitted a Paragraph IV certification as to the '302 patent, claiming that it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

127. On January 27, 2016, Jazz sued Roxane in the District of New Jersey, Case No. 2:16-cv-00469. Jazz alleged that Roxane's ANDA infringed '302 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay on the FDA's ability to approve Roxane's ANDA.

128. Roxane asserted affirmative defenses and counterclaims of non-infringement and invalidity.

129. On March 24, 2016, *Roxane VIII* was consolidated with *Roxane VI*, Case No. 2:15-cv-01360 because the '302 patent was related to and from the same patent family as the '306 patent.

9. Roxane IX

130. On or about January 9, 2015, Roxane notified Jazz that it had filed a Paragraph IV certification as to the '963 patent, claiming that it was invalid, unenforceable, or not infringed by Roxane's ANDA product.

[39] 2:15-cv-03684, ECF No. 7, ¶¶ 47, 49.

131. On August 12, 2016, Jazz sued Roxane in the District of New Jersey, No. 2:16-cv-04971, for a ninth and final time. Jazz alleged that Roxane's ANDA infringed '963 patent. Jazz's filing of the lawsuit—irrespective of its prospects of success—triggered an automatic 30-month stay of the FDA's ability to approve Roxane's ANDA.

132. Roxane moved to dismiss Jazz's claim of infringement of the '963 patent, arguing that it encompassed an unpatentable abstract idea.[40] The patent litigation was dismissed before the court could rule on the motion.

* * * *

133. Trial in the consolidated *Roxane I* patent action was scheduled to begin May 1, 2017. On March 17, 2017, parties jointly submitted a list of issues to be tried.[41]

134. However, prior to the start of trial, on April 5, 2017, Jazz and Roxane settled their outstanding patent litigations.

10. Jazz sues other generic manufacturers seeking FDA approval to sell generic Xyrem.

135. Jazz also filed numerous patent infringement lawsuits against eight other would-be generic manufacturers of generic Xyrem. Among those sued were: (1) Amneal Pharmaceuticals, LLC; (2) Par Pharmaceutical, Inc.; (3) Ranbaxy Laboratories Ltd. and Ranbaxy Inc.; (4) Watson Laboratories, Inc.; (5) Wockhardt Bio AG, Wockhardt Limited, and Wockhardt USA LLC; (6) Lupin Ltd. and Lupin Pharmaceuticals, Inc.; and (7) Mallinckrodt plc. *See Jazz Pharms., Inc. v. Amneal Pharms., LLC*, No. 2:13-cv-00391 (D.N.J.) (consolidated); *Jazz Pharms., Inc. v. Par Pharm., Inc.*, No. 2:13-cv-07884 (D.N.J.); *Jazz Pharms., Inc. v. Ranbaxy Labs. Ltd.*, No. 2:14-cv-4467 (D.N.J.); *Jazz Pharms., Inc. v. Watson Labs., Inc.*, No. 2:14-cv-

[40] 2:16-cv-04971, ECF No. 20.

[41] 2:10-cv-06108, ECF No. 506.

7757 (D.N.J.); *Jazz Pharms., Inc. v. Lupin Ltd.*, No. 2:15-cv-06548 (D.N.J.); *Jazz Pharms., Inc. v. Wockhardt Bio AG*, No. 2:15-cv-05619 (D.N.J.); *Jazz Pharms., Inc. v. Mallinckrodt plc*, No. 2:18-cv-00029 (D.N.J.).

136. The filing of patent infringement lawsuits against each of these generic companies triggered an automatic 30-month stay on the FDA's ability to approve their ANDAs.

137. Each case settled in the middle of discovery, before any claims construction hearing or trial was held.

11. The PTO invalidates the Xyrem REMS Patents in *inter partes* review.

138. While generic manufacturers were fighting Jazz's multitude of patent infringement lawsuits in federal court, some opened a second front against Jazz's weak Xyrem REMS Patents.

139. Par Pharmaceutical and Amneal Pharmaceuticals petitioned the Patent Trial and Appeal Board ("PTAB") for *inter partes* review ("IPRs") on each of the Xyrem REMS Patents. IPRs are initiated when "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[42]

140. In each instance, the PTAB found that one or more claims of each Xyrem REMS Patent were unpatentable for reasons of obviousness in light of prior art.[43]

[42] 35 U.S.C. § 314(a).

[43] *Par Pharm. Inc. v. Jazz Pharms. Inc.*, 2016 WL 7985457 (PTAB July 27, 2016) (finding claims 1-16 of the '059 patent were unpatentable); *Par Pharm. Inc. v. Jazz Pharms. Inc.*, 2016 WL 7998375 (PTAB July 27, 2016) (finding claims 1-8 of the '106 patent were unpatentable); *Par Pharm. Inc. v. Jazz Pharms. Inc.*, 2016 WL 7985458 (PTAB July 27, 2016) (finding claims 1-11 of the '730 patent and claims 1-15 of the '988 patent were unpatentable); *Par Pharm. Inc. v. Jazz Pharms. Inc.*, 2016 WL 79854759 (PTAB July 27, 2016) (finding claims 1-6 of the '107 patent were unpatentable); *Amneal Pharms. LLC v. Jazz Pharms. Inc.*, 2016 WL 8115064 (PTAB July 27, 2016) (finding claims 1-26 of the '182 patent were unpatentable); *Amneal Pharms. LLC v. Jazz Pharms., Inc.*, 2017 WL 1096638 (PTAB Mar. 22, 2017) (finding claims 24, 26, and 27 of the '963 patent were unpatentable).

141. On July 31, 2018, the Federal Circuit affirmed the PTAB's rulings invalidating each of the Xyrem REMS Patents.[44]

B. Jazz Abused REMS Requirements Causing Delay in the Approval of Roxane's ANDA.

142. In addition to filing abusive, serial infringement lawsuits against Roxane and other would-be generic competitors, Jazz also used the REMS process as means to frustrate generics obliged to negotiate a single shared system ("SSS") under REMS and delay approval of pending ANDAs for generic Xyrem.

1. Jazz delayed the development of Xyrem REMS through its inconsistent positions before the FDA.

143. As noted above, when Xyrem was approved, it was subject to a RiskMAP. The original RiskMAP called for limited distribution of Xyrem through a single pharmacy company.

144. After the passage of the FDAAA, Jazz was required to submit a REMS to replace its then existing RiskMAP, which it did in August 2008.

145. In connection with its transition from a RiskMAP to a REMS, Jazz petitioned the FDA to "remove the restriction to a single pharmacy and instead allow certification of multiple pharmacies."[45] Jazz justified this change by arguing that it would "'increase patient access without compromising patient safety.'"[46] Jazz also argued that "the single pharmacy program in existence . . . 'imposes numerous impediments to patient access to Xyrem, possibly depriving narcolepsy patients of an important medication to control their [excessive daytime sleepiness] and cataplexy and potentially affect their lives dramatically.'"[47]

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[44] *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347 (Fed. Cir. 2018).

[45] FDA Ltr. re Xyrem REMS SSS Waiver, at 6.

[46] *Id.*

[47] *Id.*

146. Jazz continued to advocate for a multiple-pharmacy REMS program in other filings with the FDA. For example, when Jazz submitted a new NDA (NDA No. 22-531) seeking FDA approval for a new Xyrem indication for fibromyalgia, Jazz proposed a REMS with multiple certified pharmacies. While the FDA declined to approve the NDA, it did so for reasons unrelated to Jazz's proposed multiple-pharmacy certification REMS program.

147. In early 2011, however, Jazz abruptly changed its position on whether multiple certified pharmacies could and should be part of a Xyrem REMS. For the first time in nearly two years, Jazz began advocating for a REMS protocol a single certified pharmacy.

148. What explains Jazz's about-face? Emerging generic competition—specifically, Roxane filed its ANDA in July 2010, and gave notice to Jazz of that filing shortly thereafter. Under an open REMS permitting the certification of multiple pharmacies, a generic competitor could choose its own pharmacy network through which to distribute generic Xyrem. By closing the Xyrem REMS to a single distributor, generic competitors would be beholden to Jazz's pharmacy of choice.

149. In August 2012, the FDA provided interim comments on Jazz's proposed REMS. Consistent with Jazz's earlier request, the FDA stated that "the final Xyrem REMS should not contain a single pharmacy limitation."[48] The FDA further stated that "the restriction to a single pharmacy was not necessary or appropriate to ensure the safe use of Xyrem, and that any pharmacy that could meet the requirements for certification could safely dispense Xyrem."[49] Significantly, the FDA accepted Jazz's prior rationale for permitting multiple pharmacy

[48] *Id.* at 6.

[49] *Id.*

certifications under the Xyrem REMS: limiting distribution to a single pharmacy "could unduly burden patient access and the health care delivery system."[50]

150. Recognizing the threat that opening the Xyrem REMS program to multiple pharmacies posed to Xyrem's profits in the advent of generic competition, Jazz alerted investors in a third quarter 2013 SEC filing that the FDA's expected modification would limit the ability of Jazz's REMS patents to block "generic competition."[51]

151. In December 2013, the FDA informed Jazz that it was removing the single pharmacy limitation to the proposed Xyrem REMS.

152. Two months later, in February 28, 2014, Jazz filed a formal request for dispute resolution, appealing the FDA's decision to modify the Xyrem REMS. Jazz argued that the FDA's decision was "not only unsupported" but "also puts patients and others at risk."[52]

153. Jazz had no legitimate basis to challenge the FDA's decision because, as noted above, Jazz had previously vigorously advocated for the same multiple-pharmacy certification system it was now rejecting. By appealing the decision, Jazz sought to stall the FDA's decision on the REMS program.

154. Following the FDA's denial of Jazz's dispute resolution request in May 2014, the next month Jazz further appealed the decision to the Director of the Office of New Drugs. In its appeal, Jazz conceded that "it might be possible for a distribution system that involves two, and perhaps more, specialty pharmacies to effectively prevent the abuse, misuse, and diversion of sodium oxybate [i.e., Xyrem]."[53]

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[50] *Id.*

[51] *Id.* at 7 (citing Form 10-Q, Sept. 30, 2013, at 54).

[52] *Id.* at 7 (citing Jazz Formal Dispute Resolution Request, Feb. 28, 2014).

[53] *Id.*

155. Yet, Jazz's litany of appeals and petitions eventually wore down the FDA. The FDA noted that "[i]n light of the significant drain on [FDA] resources posed by the dispute, and the fact that the outcome of Jazz's challenge to the [FDA's] legal authority to require a modification to a 'deemed REMS' had the potential to affect only a small number of drug products, the [FDA] decided to approve the REMS Jazz had proposed (i.e., with the single, central pharmacy limitation), and deny the dispute as moot."[54]

156. However, in denying the appeal as moot, Dr. Jenkins, the FDA's Director of the Office of New Drugs, stated:

> Our action approving the REMS submitted by Jazz should not be construed or understood as agreement with Jazz that limiting dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh the risks under 505-1 of the FD&C Act. ***We continue to be concerned that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system***.[55]

157. Indeed, so unique was Jazz's position on the single pharmacy REMS program that the FDA noted that "***No other currently approved REMS requires a sponsor to limit dispensing to a single pharmacy***." [56]

2. <u>Jazz stonewalled generic rivals and FDA in developing an SSS REMS for Xyrem.</u>

158. Generic rivals, including Amneal Pharmaceuticals, Ohm Laboratories (part of Sun Pharmaceuticals), and Roxane, seeking to work with Jazz on the development of an SSS—which they were required to do by law—were similarly subjected to Jazz's untenable negotiating positions and delay.

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[54] *Id.* at 7–8.

[55] *Id.* at 8 (emphasis added).

[56] *Id.* (emphasis added).

159. Roxane first contacted Jazz about the development of an SSS REMS on October 12, 2012. For months, Roxane negotiated with Jazz on the development of an SSS but to no avail.

160. In an attempt to accelerate the progress of the SSS negotiations between Jazz and Roxane, on January 23, 2014, the FDA hosted a meeting to facilitate the development of an SSS REMS for Xyrem and Xyrem generics. Roxane provided a timetable for certain deliverables, including the execution of a confidentiality and disclosure agreement ("CDA") within 30 days of the meeting. The FDA requested that the Jazz and Roxane submit bi-weekly updates on the status of negotiations.

161. Four days after the FDA meeting, on January 28, 2014, Roxane provided a draft of the CDA to Jazz. On February 14, 2014, Jazz returned a substantially revised CDA. Negotiations over the CDA ensued for more than *seven* months. The CDA was not signed until August 2014.

162. After learning of Jazz's dispute resolution request, in March 2014, Roxane expressed concern that "'any dispute resolution process will be a protracted matter which will further delay the implementation of a REMS.'"[57] The FDA, in response, requested that the parties continue their negotiations. However, because the FDA lacked any enforcement mechanism to bring the parties to an agreement within a date certain, Jazz used this loophole to do exactly what Roxane feared Jazz would do—delay and extend negotiations, which in turn, would delay the approval of an SSS REMS for generic Xyrem. And because generic approval was contingent on the development of such a REMS, any delay caused by Jazz's stonewalling would also delay FDA final approval for generic Xyrem ANDAs.

[57] *Id.* at 9 (citing Email from Gregory Hicks to FDA, Mar. 12, 2014).

163. The negotiations between Jazz and would-be generic competitors over the development of an SSS REMS continued without success for over a year. By October 2015, the parties were at impasse on several threshold issues that precluded the development of an SSS REMS. Indeed, Roxane and Jazz had not even agreed on the process for negotiating the SSS. Jazz contended that the generics were refusing to proceed with "legal and operational discussions on parallel tracks, which would require integration of operational personnel into legal discussions."[58] This position, however, was a red herring because the CDA precluded the generics from using any information from the negotiations for an SSS REMS in the possible future development of a separate REMS for the generics. As a result, if the generic companies' operations staff was involved in the discussions regarding the legal agreement with Jazz, those individuals would have to be walled-off from doing any work in developing a separate REMS. Accordingly, Jazz was forcing its generic rivals into a no-win situation.

164. Frustrated by Jazz's recalcitrance in negotiations, Roxane and other generic rivals stated their intention to seek a waiver for the SSS REMS.

165. Realizing that a waiver, if granted, would clear a major roadblock to FDA final approval, on December 4, 2015, Jazz opposed the waiver request. Jazz reiterated its position that a single, central pharmacy was the only acceptable REMS protocol—a position that, as noted above, contradicted Jazz's previous position when transitioning from a RiskMAP to a REMS.[59]

166. Roxane formally submitted a request for the FDA to waive the SSS requirement on December 28, 2016.

[58] *Id.* at 10.

[59] *Id.*

C. The FDA Grants Final Approval of Roxane's ANDA and Grants Waiver on SSS for Xyrem REMS

167. Despite Jazz's efforts to use the REMS process to arrest the approval of Roxane's and other generics' pending ANDAs, on January 17, 2017, the FDA finally approved Roxane's ANDA. On the same date, it also issued granted Roxane and other generics a waiver from the SSS requirement under the FDCA.

168. In the final approval letter, the FDA noted that although Roxane's ANDA was not tentatively approved within the 30-month period described, Roxane did not forfeit its 180-day exclusivity by operation of the provisions in the Food and Drug Administration Safety and Innovation Act.

169. The final approval letter also stated that Roxane's REMS program, which consisted of a Medication Guide, ETASU, and an implementation system, was also approved. Concurrently with the final approval letter, Roxane also received a formal decision from the FDA waiving the need for an SSS REMS for its generic Xyrem product. In its decision to waive the SSS requirements, the FDA noted that the waiver came after *four years* of unsuccessful negotiations with Jazz. Recognizing the lack of incentive Jazz had in cooperating to develop an SSS REMS, the FDA also stated that "[t]here are obvious incentives for any innovator company, ***including Jazz, to delay generic competition, including by failing to agree on SSS REMS terms***."[60]

170. The FDA further stated that it "ha[d] been waiting to approve any sodium oxybate ANDAs pending development of an SSS REMS."[61] Recognizing the effects of this delay, the

[60] *Id.* at 17 (emphasis added).

[61] *Id.* at 16.

FDA stated that the delay may have "***impose[d] a substantial cost to the U.S. healthcare system, as Xyrem remained, until now, shielded from generic competition***."[62]

171. With final approval of its ANDA and REMS program in hand, Roxane was finally able to launch its generic Xyrem product. However, as explained below, before it could launch its product and bring the benefits of increased competition, Jazz and Roxane settled their ongoing patent litigation through the use of an unlawful reverse payment.

D. Jazz and Roxane Enter an Unlawful Pay for Delay Agreement

172. As noted above, trial in the consolidated Jazz-Roxane Xyrem patent litigation was scheduled to begin May 1, 2017. On April 5, 2017, though, Jazz and Roxane settled their seven-year long patent litigation by executing three interrelated and contemporaneous agreements: the Settlement Agreement, the License Agreement, and the AG Agreement (collectively, the "patent settlement").

173. Under the patent settlement, Jazz granted Roxane a license to sell an AG of Xyrem beginning January 1, 2023 or earlier under certain circumstances. Although these other circumstances have not been publicly disclosed, it is customary for the brand manufacturer in Hatch-Waxman settlements to permit the settling generic to accelerate the timing of its launch if the brand manufacturers' patents are declared invalid or unenforceable prior to the generic's agreed upon entry date.

174. The initial term of Roxane's AG license is six months—*i.e.*, the duration of Roxane's 180-day generic exclusivity. Roxane, however, has the option to continue its sale of the AG for a total of five years. During the initial six-month period, Roxane will pay Jazz a royalty on Roxane's net sales of the Xyrem AG. Roxane will also pay Jazz for the supply of the

[62] Xyrem REMS Waiver Ltr. at 16 n.49 (emphasis added).

AG and a portion of the cost associated with Jazz's REMS program for Xyrem. In addition, under the agreement, Jazz refrained from launching its own AG of Xyrem during Roxane's six-months of AG sales.

175. Notably, only after the expiration of the initial six-month term of AG sales is Roxane permitted to launch a generic version of Xyrem under its ANDA.[63]

176. These terms demonstrate that Jazz and Roxane's patent settlement is an unlawful pay-for-delay agreement. As explained in further detail below, Jazz's agreement not to launch its own AG will provide hundreds of millions of dollars to Roxane that it would not have obtained but for its agreement with Jazz. Further, Jazz has continued to preserve the value of the no-AG agreement to Roxane by refusing to permit other settling generics from obtaining similar terms. For example, in Jazz's Xyrem patent settlements with Ranbaxy and Wockhardt, it only permitted these generics to enter the market on December 31, 2025.

177. Even when Jazz licensed a Xyrem AG to other would-be generic competitors, it took care not to negotiate settlements that permitted those AG licenses to run concurrently with Roxane's. Jazz's settlement with Par is instructive. Jazz granted Par a license to sell limited quantities of a Xyrem AG, but in doing so, only permitted those generics' license to commence on July 1, 2023—the *181st* day after Roxane was permitted to launch its Xyrem AG. The limited nature of the Par license provides additional value to Roxane because in the event that Roxane continues licensing the AG from Jazz after its 180-day exclusivity, it will face only limited competition from other generics. Such agreements worked to the financial benefit of Jazz, too,

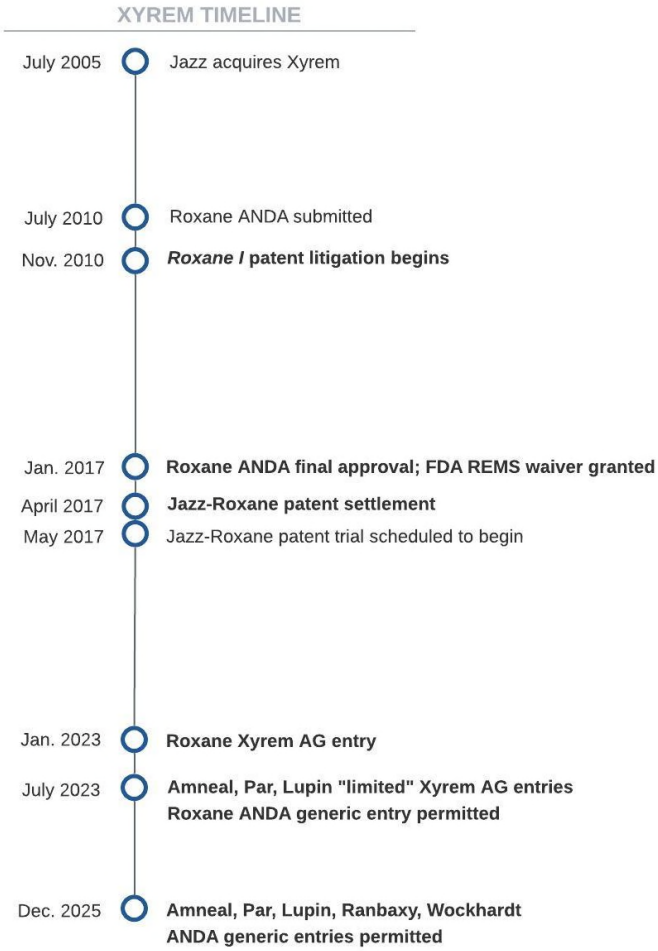
[63] https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-reaches-settlement-with-hikma-pharmaceuticals-related-to-xyrem-patent-litigation-300435524.html.

because it also will benefit from less robust competition after the expiry of Roxane's 180-day exclusivity.

178. Jazz entered into similar settlements with Lupin and Amneal permitting them to launch "limited quantities" of a Xyrem AG after Hikma's 180-day exclusivity period expires. Without the benefit of discovery or the settlement agreements themselves, it is unclear at this time whether these agreements have anticompetitive terms.

179. The fact that Roxane will owe a royalty to Jazz under its AG license and must pay Jazz for the AG supply does not change the fact that Jazz's no-AG agreement is a large payment to Roxane exchange for Roxane's agreement to delay market entry for nearly six years. The royalty here simply acts as a tax on Roxane. In order for Roxane to maximize its profits during its 180-day exclusivity period, it will keep the prices of its Xyrem AG to near parity with Xyrem. Thus, the royalty serves to induce Roxane to keep its prices for the AG higher than it otherwise would have, had it been allowed to market a generic under its own ANDA.

180. Jazz's anticompetitive conduct has effectively prevented the entry of any true (non-AG) generic until July 2023 at the earliest with multiple true generics only appearing at year-end 2025. Accordingly, by the time Roxane is capable of launching the first true generic in July 2023, as the following timeline demonstrates, Jazz will have maintained its domination over the Xyrem market for nearly 20 years and made many billions of dollars over that time period for a drug it obtained for little over $120 million.



1. <u>The value of the no-AG agreement to Jazz.</u>

181. After generic entry in January 2023, Jazz would have lost at least 80% of its branded sales during Roxane's 180-day exclusivity period. But without generic entry, Jazz kept all those sales—and continued to enjoy those branded sales until the end of 2016.

182. Because Roxane was the first ANDA filer, its agreement not to launch generic Xyrem until January 2023 created a competition bottleneck where no other generic company could market its own ANDA generic of Xyrem product until 180 days after Roxane launched a generic Xyrem product. In establishing a bottleneck using Roxane, Jazz maximized the potential

for it to maintain its monopoly on Xyrem for about six years longer than it otherwise would have.

183. Sales of Xyrem in 2017 were $1.186 billion. Based on well-documented trends relating to the sales and pricing of pharmaceuticals upon the emergence of generic competition, Jazz's AG and Roxane's generic, combined, would have captured at least 80% of the amount of branded sales in the first six months, with each of those companies splitting the generic sales 50/50 (therefore, 40% each of the brand share). The Jazz AG and Roxane's generic would have sold at around 40%-50% of the price of branded Xyrem. Using these assumptions and assuming Xyrem sales did not grow after 2017—which they did, to about $1.64 billion annually (as of 2019)—a conservative estimate (because it assumes that Jazz foresaw no additional sales growth, which is unlikely) of the value of Jazz's AG in the first six months following generic entry is that it would have been worth at least $119 million.[64] Had Jazz predicted that sales would continue to grow to its present levels (*i.e.*, about $1.64 billion annually), a Jazz AG would be expected to be worth at least $164 million to Jazz.[65]

184. The estimated value of the no-AG agreement far exceeds the litigation costs Jazz saved by settling its patent litigation with Roxane. At the time of settlement, Defendants were only a few weeks from trial, meaning that much of the expense of litigation had already been incurred. Accordingly, the no-AG agreement is a large, unjustified *Actavis*-type reverse payment.

2. The value of the no-AG agreement to Roxane.

185. The value of the no-AG agreement from Roxane's perspective is a matter of estimating the additional sales it made during its six-month generic exclusivity period in 2016

[64] $1.186 billion * 0.5 [for the first six months] * 0.4 [share of the generic sales] * 0.5 [generic price].

[65] $1.64 billion * 0.5 [for the first six months] * 0.4 [share of the generic sales] * 0.5 [generic price].

compared to the sales it would have made in the first six months of generic competition starting in January 2023 when, without the benefit of the no-AG agreement, it would have faced competition from a Jazz Xyrem AG.

186. Under competitive conditions, the calculation of Roxane's sales during the first six months of generic competition starting in January 2023 is identical to the calculation for Jazz's Xyrem AG during this period, because the same assumptions apply to Roxane's generic as to Jazz's. Thus, when facing competition from Jazz's Xyrem AG, the expected value of Roxane's generic Xyrem would have been between approximately $119 million (if Xyrem sales remained constant after 2017) to $150 million (if Roxane accurately predicted Xyrem sales to grow as they did).

187. Under the anticompetitive conditions created by the no-AG agreement, however, Roxane stood in a far better position financially. With the no-AG agreement, Roxane will (a) receive 100% of the generic sales in the first six months of generic launch (because there was no AG taking market share); and (b) be able to sell that generic during those months for about 90% (and not 40%–50%) of the branded price because there was no AG driving down price.

188. Without competition from Jazz's AG, Roxane's Xyrem AG will stand alone and therefore can expect to capture at least 80% of the sales of the branded product in 2023, and likely would have priced its generic product at about 80%-90% of the brand's price. As a result, during its six-month exclusivity period in 2023, without competition from Jazz's AG, Roxane's Xyrem AG will likely realize at least $524.8 million in generic sales.[66]

[66] $1.64 billion * 0.5 [for the first 6 months] * 0.8 [generic penetration of Hikma's Xyrem AG] * 0.8 [generic price].

189. Thus, the no-AG agreement with Jazz delaying Roxane's entry into the market until January 2023 is worth at least $374.8 million in *additional* sales to Roxane, compared to sales it would have made without the benefit of the no-AG agreement ($524.8 million less $150 million). The no-AG payment from Jazz to Roxane made delayed generic entry will be incredibly lucrative for Roxane.

190. The value of the no-AG agreement far exceeds any litigation costs Roxane saved by agreeing to settle its patent litigation with Jazz. As noted above, at the time of settlement, Defendants were only a few weeks from trial, meaning that much of the expense of litigation had already been incurred. Accordingly, the no-AG agreement is a large, unjustified *Actavis*-type reverse payment.

3. Upon announcing its no-AG agreement with Roxane, Jazz's stocks soar.

191. Further corroboration that the Jazz-Roxane patent settlement contained an unlawful reverse payment to Roxane can be shown in the way the stock market reacted to the news of the Jazz-Roxane patent settlement.

192. Academic literature has demonstrated that increases in a brand pharmaceutical company's stock price, and stock trading volumes upon the announcement of a patent settlement with a generic manufacturer, is a strong signal that the settlement contained a reverse payment. Market participants have an expectation of when they expect generic competition to enter the market—either through a settlement or litigation victory. That information is incorporated into the trading price and trading volumes of a particular company's stock.

193. When a brand manufacturer announces a patent settlement with a generic rival that calls for a delayed generic entry beyond what market participants expected, that new information causes the market to react. Thus when a settlement announcement precipitates

significant increases in the brand company's stock price and trading volumes, it creates a strong inference that the settling parties received something of significant value: in the case of the brand, an extended monopoly.

194. The figures below reflect Jazz's historical stock prices and trading volume in the week prior to, and the week following, the announcement of the Jazz-Roxane patent settlement on April 5, 2017. The deal was announced at or after the end of trading on April 5, 2017, meaning that the market did not fully react to the announcement until the market reopened on April 6 (marked in yellow highlight and bold below).

FIGURE 1: JAZZ STOCK PRICE / TRADING VOLUME TABLE

Date	Open	High	Low	Close	Volume
03/27/2017	141.59	148.14	141.14	146.98	670,400
03/28/2017	146.38	147.28	145.56	145.91	461,400
03/29/2017	145.51	146.82	145.13	146.05	464,900
03/30/2017	146.52	146.83	145.58	145.68	303,500
03/31/2017	145.74	146.97	144.95	145.13	509,500
04/03/2017	144.55	145.36	141.9	142.91	554,600
04/04/2017	142.63	144.26	142.17	143.21	319,100
04/05/2017	144.18	144.18	139.72	140.65	669,700
04/06/2017	**150**	**154.99**	**149.63**	**153.88**	**2,733,900**
04/07/2017	152.81	155.6	151.24	153.78	643,900
04/10/2017	152.24	153.54	151.7	152.88	447,500
04/11/2017	152.12	154.17	151.32	152.98	648,300
04/12/2017	153.57	153.57	151.15	152.21	419,000
04/13/2017	151.77	154.38	151.71	153.11	329,800

FIGURE 2: JAZZ STOCK PRICE MOVEMENT GRAPH

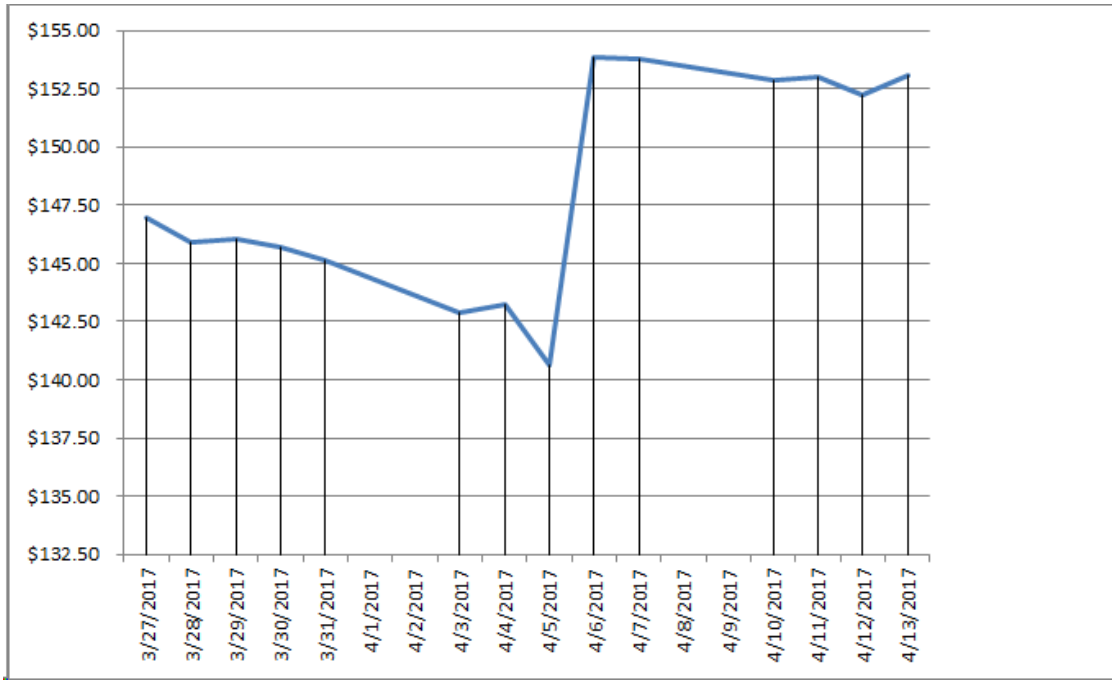
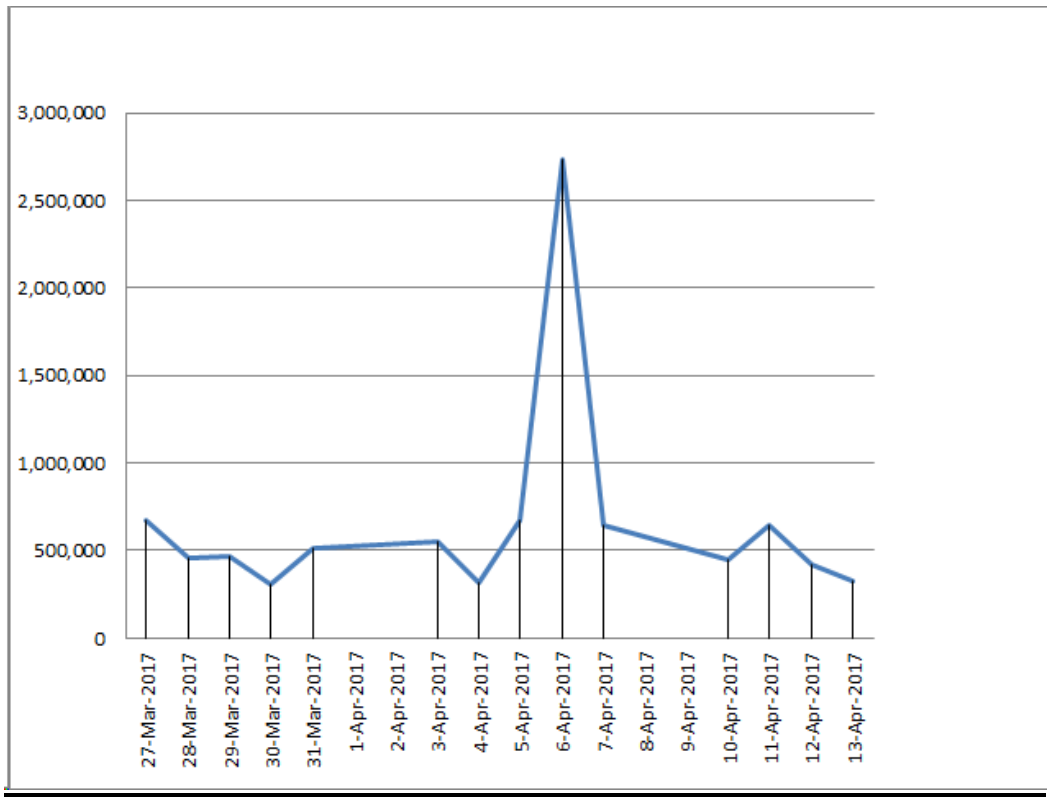


FIGURE 3: JAZZ STOCK TRADING VOLUME



195. As shown in Figures 1 and 2 above, on April 5, 2017, Jazz's stock price closed at $140.65/share. The announcement of the Jazz-Roxane settlement after the market closed caused post-close trading prices of Jazz's stock to increase substantially. On April 6, 2017, the market open price for Jazz's stock was $150/share—an increase of 6.4% over Jazz's stock price at market close the day prior. By market close of April 6, Jazz's stock price had increased to $153.88, an increase of over 9.4% over Jazz's stock price at market close the day prior. By comparison, the largest daily movement in Jazz's stock price in the week leading up to April 6, 2017 was approximately 1.5%.

196. Trading volumes of Jazz's stock also increased significantly upon the announcement of the Jazz-Roxane patent settlement, as shown in Figures 1 and 3. At the end of the trading day on April 5, 2017, trading volume of Jazz's stock was 669,700. By the end of the trading day on April 6, 2017, trading volume of Jazz's stock soared to over 2.7 million—an increase of 121% over the prior day's trading volume. By comparison, the largest daily swing in Jazz's trading volume in the week leading up to April 6, 2017, was approximately 36.9%.

197. These movements in both stock price and volume traded when the Jazz-Roxane patent settlement was announced are powerful evidence that the settlement between Jazz and Roxane contained a large reverse payment.

MARKET POWER AND MARKET DEFINITION

198. To the extent that Plaintiff may be required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is the market for branded and generic versions of sodium oxybate solution.

199. At all relevant times, Jazz had, and continues to have, substantial market power and/or monopoly power in the market for branded and generic versions of sodium oxybate oral

solution (Xyrem). Jazz has maintained and continues to maintain 100% market share in the market for branded and generic versions of sodium oxybate solution.

200. At all relevant times, Jazz has exercised, and continues to exercise, the power to exclude and restrict competition in the market for branded and generic versions of Xyrem.

201. At all relevant times, there were, and continue to be, high barriers to entry with respect to competition in the market for branded and generic versions of Xyrem in the form of patent and other regulatory protections, as well as high startup costs.

202. At all relevant times, Jazz has sold Xyrem at prices well in excess of the competitive price and has maintained gross margins on Xyrem sales in excess of 90%.

203. A small but significant, non-transitory price increase for Xyrem by Jazz would not have caused a significant loss of sales to other narcolepsy treatments sufficient to make such a price increase unprofitable.

204. Xyrem did not exhibit significant, positive cross-elasticity of demand with respect to price, with any narcolepsy treatments currently on the market.

205. In fact, Jazz raised prices of Xyrem immediately after acquiring the drug from Orphan Medical and continued to increase Xyrem prices through the present. The table below shows Xyrem's historic per unit (1 mg/mL) Wholesale Acquisition Cost ("WAC") from February 2015 to the present:

FIGURE 4: HISTORIC XYREM WAC

Date	Per Unit WAC
02/15/2015	18.8399
02/02/2016	20.6278
01/05/2017	21.9665
07/07/2017	22.4058
01/05/2018	23.9742
01/04/2019	25.6524
07/10/2019	26.1655
01/08/2020	28.3895
06/24/2020	28.3895

206. The consistent WAC increases demonstrates that Xyrem does not have any close competitors and that Jazz can and does profitably increase prices without competitive restraints.

207. Xyrem is not reasonably interchangeable with any products other than A-rated generic versions of Xyrem.

208. The existence of non-Xyrem narcolepsy treatments did not constrain Jazz's ability to raise or maintain Xyrem's supracompetitive prices, and therefore those other drug products are not in the same relevant antitrust market with Xyrem.

209. Therapeutic alternatives are not the same as economic alternatives. Functional similarities between Xyrem and non-Xyrem narcolepsy treatments are insufficient to permit inclusion of those other narcolepsy treatments in the relevant market with Xyrem. To be an economic substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on the prices and sales of another product, so that the price of that other product cannot be maintained at supracompetitive levels. No other narcolepsy treatments apart from generic

versions of Xyrem could have taken away sufficient sales from Xyrem to prevent Jazz from raising or maintaining the price of Xyrem at supracompetitive levels.

210. Xyrem is also not reasonably interchangeable with any products other than generic versions of Xyrem because both Xyrem and its generic equivalents have different attributes significantly differentiating them from other narcolepsy treatments and making them unique. Xyrem and its generic equivalents are chemically and therapeutically distinct from other narcolepsy treatments, including stimulants (modafinil and armodafinil), selective serotonin reuptake inhibitors (fluoxetine and venlafaxine), and tricyclic antidepressants (protriptyline, imipramine, and clomipramine). Indeed, Xyrem is highly effective for treating cataplexy symptoms in patients with narcolepsy. Further, the FDA does not consider Xyrem and its generic equivalents interchangeable with other narcolepsy treatments.

211. Price does not typically drive prescriptions for medications, including those for narcolepsy treatments. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including sodium oxybate oral solution, to patients without a prescription written by a doctor. Patients and third-party payors have the obligation to pay for the pharmaceutical product, but it is ultimately the patients' doctors who choose which product the patient will buy.

212. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals. Moreover, even when they are aware of the costs, they are insensitive to prices because they do not pay for the products. The result is a marketplace in which price plays a comparatively smaller role in product selection.

213. Thus, unlike many consumer products for which consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs, such as narcolepsy treatments, is generally made by the physician, not by consumers of those products. Consequently, despite the existence of a number of different narcolepsy treatments a physician could have started a patient on, or in theory could switch a patient to, once the physician and patient find one that is effective and well tolerated, it is unlikely that the patient will switch to a different narcolepsy treatments based on variations of price.

214. Doctors generally select narcolepsy treatments based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Xyrem to other narcolepsy treatments.

215. Accordingly, Jazz needs to control only Xyrem and its generic equivalents, and no other products, in order to profitably maintain supracompetitive prices for Xyrem. Only the market entry of competing, generic versions of Xyrem will render Jazz unable to profitably maintain its supracompetitive prices of Xyrem.

216. The relevant geographic market is the United States and its territories.

DEFENDANTS' ANTICOMPETITIVE CONDUCT INJURED PLAINTIFF AND THE CLASSES

217. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Xyrem from generic competition. But for the pay-for-delay agreement, Roxane would have entered the market earlier than January 2023.

218. But for Defendants' illegal conduct, generic competition would have forced decreases in the prices of Xyrem, as price competition among the suppliers of branded and generic versions of Xyrem would have been intense.

219. But for Defendants' illegal conduct, Plaintiff and members of the Classes would have paid less for branded and generic versions of Xyrem. Defendants' conduct proximately caused Plaintiff's and the Classes' injuries because they have paid and continue to pay hundreds of millions of dollars in overcharges on purchases of Xyrem.

220. As a result of the delay in generic competition brought about by Defendants' anticompetitive scheme, Plaintiff and members of the Classes paid more for Xyrem than they would have paid absent Defendants' illegal conduct.

221. Upon entering the market, generic equivalents of brand name drugs are priced below the branded drug. When multiple generic products are on the market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

222. If generic competition for Xyrem had not been unlawfully delayed, Plaintiff and members of the Class would have paid less for both branded and generic versions Xyrem by: (a) substituting their purchases of Xyrem with less-expensive generic versions of Xyrem; (b) purchasing generic Xyrem at lower prices sooner; and (c) purchasing branded Xyrem at a reduced price.

223. Defendants' efforts to restrain competition in the market for branded and generic versions of Xyrem have substantially affected interstate commerce.

224. At all material times, Jazz manufactured, promoted, distributed, and sold substantial amounts of Xyrem in a continuous and uninterrupted flow of commerce across state lines and throughout the United States.

225. At all material times, Jazz transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of Xyrem.

226. Defendants' pay-for-delay agreement has enabled Jazz to continue charging end payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

227. These prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

CLASS ACTION ALLEGATIONS

228. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, seeking relief on behalf of the following classes (the "Classes"):

The Nationwide Injunction Class

All persons or entities in the United States and its territories that purchased or reimbursed brand or generic Xyrem, beginning at least as early as April 5, 2017 until the effects of Defendants' conduct cease (the "Class Period").

The Damages Class

All persons or entities that purchased or reimbursed brand or generic Xyrem, beginning at least as early as April 5, 2017 until the effects of Defendants' conduct cease in any of the following states or territories: Arizona, California, Connecticut, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, or Wisconsin.

229. The following persons and entities are excluded from each of the above-described proposed Classes:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities (including state and federal Medicaid programs), except for government-funded employee benefit plans;

(c) All persons or entities who purchased Xyrem for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

(h) The Court, Court personnel and any member of their immediate families.

230. Members of the Classes are so numerous and geographically dispersed that joinder of all members of the Class is impracticable. Plaintiff believes that there are thousands of members of the Classes widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Classes are readily identifiable from industry data and information and record maintained by pharmacy benefit managers, retail and mail-order pharmacies, and other sources.

231. Plaintiff's claims are typical of the claims of members of the Classes. Plaintiff and members of the Classes were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for Xyrem and were deprived of the benefits of earlier and more

robust competition from cheaper generic equivalents of Xyrem as a result of Defendants' wrongful conduct.

232. Plaintiff will fairly and adequately protect and represent the interests of the members of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

233. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation and with experience in class action antitrust litigation involving pharmaceutical products.

234. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to the Classes, making overcharge damages with respect to the Classes as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

235. Questions of law and fact common to the Classes include:

(a) Whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

(b) To the extent such justifications exist, whether there were less restrictive means of achieving them;

(c) Whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market;

(d) Whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(e) Whether Defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Classes;

(f) Whether Jazz and Roxane conspired to delay generic competition for Xyrem;

(g) Whether, pursuant to the pay-for-delay agreement, Jazz's promise not to compete against Roxane's generic product constituted a payment;

(h) Whether Jazz's agreement with Roxane was necessary to yield some cognizable, non-pretextual procompetitive benefit;

(i) Whether Jazz's compensation to Roxane was large and unexplained;

(j) Whether the pay-for-delay agreement a bottleneck to further delay generic competition for Roxane;

(k) Whether the pay-for-delay agreement harmed competition;

(l) Whether Jazz possessed the ability to control prices and/or exclude competition for Xyrem;

(m) Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of generic Xyrem;

(n) Determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic conduct caused;

(o) The quantum of overcharges paid by the Damages Class in the aggregate; and

(p) The scope and nature of the equitable relief for the Nationwide Injunction Class.

236. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

237. Plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

CONTINUING VIOLATION

238. This Complaint alleges an ongoing restraint of competition in the market for sodium oxybate solution, and Plaintiff and members of the Damages Class (defined below) are entitled to recover damages suffered within the applicable limitations periods**.**

239. A claim for damages accrued each time a Plaintiff purchased brand or generic sodium oxybate solution at a supra-competitive price as a result of Defendants' anticompetitive conduct. And each sale of brand or generic sodium oxybate solution at a supra-competitive price constituted another overt act in furtherance of Defendants' continuing anticompetitive scheme. Accordingly, Plaintiffs are entitled to recover all damages suffered by Plaintiff and members of the Damages Class within the applicable limitation period for the statutory claims pleaded below.

CLAIMS FOR RELIEF

COUNT I
(Contract, Combination or Conspiracy in Violation of the Sherman Act, 15 U.S.C. § 1 on Behalf of the Nationwide Injunction Class)

240. Plaintiff incorporates the preceding paragraphs by reference.

241. On April 5, 2017, Jazz and Roxane entered into a pay-for-delay agreement, a continuing illegal contract, combination, and restraint of trade, under which Jazz paid Roxane substantial consideration in exchange for Roxane's agreement to delay bringing its generic version of Xyrem to the market, the purpose and effect of which was to:

(a) Delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra-competitive profits;

(b) Keep an authorized generic off the market during Roxane's 180-day generic exclusivity period, thereby allowing Roxane to monopolize the generic market for Xyrem during that period and allowing Roxane to make supra-competitive profits;

(c) Allocate 100% of U.S. generic Xyrem sales to Roxane during the first 180 days of generic sales; and

(d) Raise and maintain the prices that Plaintiff and the members of Classes would pay for Xyrem at supra-competitive levels until at least July 2023.

242. Jazz and Roxane are liable for this pay-for-delay agreement under a "rule of reason" standard under the antitrust laws because there is no legitimate, non-pretextual, pro-competitive business justification for this pay-for-delay agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

243. As a result of Defendants' conduct, Plaintiff and the Nationwide Injunction Class Members have been harmed by having to pay higher prices for Xyrem and its AA-rated generic equivalents than they would have paid in the absence Defendants' anticompetitive conduct.

244. Plaintiff and Nationwide Injunction Class Members are entitled to equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15

U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

COUNT II
(Monopolization in Violation of Sherman Act, 15 U.S.C. § 2
Against Jazz on Behalf of the Nationwide Injunction Class)

245. Plaintiff incorporates the preceding paragraphs by reference.

246. Jazz has knowingly engaged in an anticompetitive scheme designed to delay and block entry of generic equivalents of Xyrem. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Xyrem. Jazz's exclusionary conduct included:

(a) improperly listing of Xyrem REMS Patents in the Orange Book, despite none claiming the Xyrem drug product or a method of using Xyrem;

(b) the filing of serial and abusive patent litigation against would-be generic competitors on improperly listed Orange Book patents and patents obtained through inequitable conduct before the PTO;

(c) abusive and dilatory conduct in the negotiation and development of a Xyrem REMS; and

(d) entering into an unlawful pay-for-delay agreement with Roxane that preserved Jazz's monopoly over brand and generic Xyrem for an additional six years.

247. Jazz's exclusionary conduct maintained Jazz's monopoly over branded and generic Xyrem until at least January 2023.

248. Plaintiff and the Nationwide Injunction Class Members have suffered harm as a result of paying higher prices for Xyrem and its generic equivalents than they would have absent Jazz's anticompetitive conduct and continuing anticompetitive conduct.

249. Plaintiff and the Nationwide Injunction Class Members have been injured in their business or property by Jazz's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Xyrem, and (2) paying higher prices for these products than they would have paid in the absence of Jazz's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Jazz's conduct unlawful.

250. Plaintiff and the Nationwide Injunction Class Members are entitled equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Jazz's unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

COUNT III
(Anticompetitive Contracts, Combinations, and Arrangements in Violation of State Antitrust Laws Against All Defendants on Behalf of the Damages Class)

251. Plaintiff incorporates the preceding paragraphs by reference.

252. On April 5, 2017, Jazz and Roxane entered into a pay-for-delay agreement, a continuing illegal contract, combination, and restraint of trade, under which Jazz paid Roxane substantial consideration in exchange for Roxane's agreement to delay bringing its generic version of Xyrem to the market, the purpose and effect of which was to:

(a) Delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra-competitive profits;

(b) Keep an authorized generic off the market during Roxane's 180-day generic exclusivity period, thereby allowing Roxane to monopolize the generic market for Xyrem during that period and allowing Roxane to make supra-competitive profits;

(c) Allocate 100% of U.S. generic Xyrem sales to Roxane during the first 180 days of generic sales; and

(d) Raise and maintain the prices that Plaintiff and the members of the Damages Class would pay for Xyrem at supra-competitive levels until at least July 2023.

253. Jazz and Roxane are liable for this pay-for-delay agreement under a "rule of reason" standard under the antitrust laws because there is no legitimate, non-pretextual, pro-competitive business justification for this pay-for-delay agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

254. Defendants' conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the Damages Class Members;

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the Damages Class Members;

(c) Conn. Gen. Stat. § 35-24, *et seq.*, with respect to purchases in Connecticut by the Damages Class Members;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Damages Class Members;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Damages Class Members;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(g) Iowa Code §§ 553, *et seq.*, with respect to purchases in Iowa by the Damages Class Members;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(i) Md. Code, Com. Law § 11-201, *et seq.*, with respect to purchases in Maryland by the Damages Class Members;

(j) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Damages Class Members;

(k) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Damages Class Members;

(l) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Damages Class Members;

(m) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(n) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Damages Class Members;

(o) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Damages Class Members, in that sales of Xyrem took place in Nevada, purchased by Nevada end payers at supracompetitive prices caused by Defendants' conduct;

(p) N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the Damages Class Members;

(q) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the Damages Class Members;

(r) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the Damages Class Members;

(s) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the Damages Class Members;

(t) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the Damages Class Members;

(u) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the Damages Class Members;

(v) R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases in Rhode Island by the Damages Class Members;

(w) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the Damages Class Members;

(x) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the Damages Class Members, with end payers in Tennessee paying substantially higher prices for Xyrem in Tennessee;

(y) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damages Class Members who are either citizens or residents of Utah;

(z) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by the Damages Class Members;

(aa) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the Damages Class Members; and

(bb) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people

of Wisconsin, with thousands of end payers in Wisconsin paying substantially higher prices for Xyrem in Wisconsin.

255. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

256. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Damages Class Members.

COUNT IV
(Monopolization and Monopoly Maintenance in Violation of State Antitrust Laws Against Jazz on Behalf of The Damages Class)

257. Plaintiff incorporates the preceding paragraphs by reference.

258. Jazz has knowingly engaged in an anticompetitive scheme designed to delay and block entry of generic equivalents of Xyrem. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Xyrem. Jazz's exclusionary conduct included:

(a) improperly listing of Xyrem REMS Patents in the Orange Book, despite none claiming the Xyrem drug product or a method of using Xyrem;

(b) the filing of serial and abusive patent litigation against would-be generic competitors on improperly listed Orange Book patents and patents obtained through inequitable conduct before the PTO;

(c) abusive and dilatory conduct in the negotiation and development of a Xyrem REMS; and

259. entering into an unlawful pay-for-delay agreement with Roxane that preserved Jazz's monopoly over brand and generic Xyrem for an addition six years.

260. Jazz's exclusionary conduct maintained Jazz's monopoly over branded and generic Xyrem until at least January 2023.

261. Plaintiff and the Damages Class Members have suffered harm as a result of paying higher prices for Xyrem and its generic equivalents than they would have absent Jazz's anticompetitive conduct and continuing anticompetitive conduct.

262. Plaintiff and the Damages Class Members have been injured in their business or property by Jazz's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Xyrem and (2) paying higher prices for these products than they would have paid in the absence of Jazz's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent and flow from that which makes Jazz's conduct unlawful.

263. Jazz's anticompetitive conduct violates the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the Damages Class Members;

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the Damages Class Members;

(c) Conn. Gen. Stat. § 35-24, *et seq.*, with respect to purchases in Connecticut by the Damages Class Members;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Damages Class Members;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Damages Class Members;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(g) Iowa Code §§ 553, *et seq.*, with respect to purchases in Iowa by the Damages Class Members;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(i) Md. Code, Com. Law § 11-201, *et seq.*, with respect to purchases in Maryland by the Damages Class Members;

(j) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Damages Class Members;

(k) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Damages Class Members;

(l) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Damages Class Members;

(m) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(n) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Damages Class Members;

(o) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Damages Class Members, in that sales of Xyrem took place in Nevada, purchased by Nevada end payers at supracompetitive prices caused by Defendants' conduct;

(p) N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the Damages Class Members;

(q) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the Damages Class Members;

(r) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the Damages Class Members;

(s) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the Damages Class Members;

(t) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the Damages Class Members;

(u) R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases in Rhode Island by the Damages Class Members;

(v) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the Damages Class Members;

(w) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the Damages Class Members;

(x) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the Damages Class Members, with end payers in Tennessee paying substantially higher prices for Xyrem in Tennessee;

(y) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damages Class Members who are either citizens or residents of Utah;

(z) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by the Damages Class Members;

(aa) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the Damages Class Members; and

(bb) Wis. Stat. §§ 133.03, *et seq*., with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end payers in Wisconsin paying substantially higher prices for Xyrem in Wisconsin.

264. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Jazz's anticompetitive conduct.

COUNT V
(Unfair and Unconscionable Conduct in Violation of State Consumer Protection Laws Against All Defendants on Behalf of the Damages Class)

265. Plaintiff incorporates the preceding paragraphs by reference.

266. On April 5, 2017, Jazz and Roxane entered into a pay-for-delay agreement, a continuing illegal contract, combination, and restraint of trade under which Jazz paid Roxane substantial consideration in exchange for Roxane's agreement to delay bringing its generic version of Xyrem to the market, the purpose and effect of which was to:

(a) Delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra-competitive profits;

(b) Keep an authorized generic off the market during Roxane's 180-day generic exclusivity period, thereby allowing Roxane to monopolize the generic market for Xyrem during that period and allowing Roxane to make supra-competitive profits;

(c) Allocate 100% of U.S. generic Xyrem sales to Roxane during the first 180 days of generic sales; and

(d) Raise and maintain the prices that Plaintiff and the members of Damages Class would pay for Xyrem at supra-competitive levels until at least July 2023.

267. Further, Jazz engaged in deceptive conduct by: (1) improperly listing the Xyrem REMS Patents in the Orange Book despite the fact that none claimed a drug product or method

of using a drug as required by regulation; (2) withholding material prior art from the PTO in the prosecution of certain patents purportedly covering Xyrem, causing the PTO to improperly issue those patents; and (3) asserting those improperly obtained patents against would-be generic rivals in multiple patent infringement suits.

268. Defendants' pay-for-delay agreement and other unlawful conduct therefore constitute unfair, unconscionable, and/or deceptive conduct in violation of the following state consumer protection statutes:

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.

269. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

270. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

271. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint.

272. As a result of Defendants' illegal agreements, Plaintiff and the Damages Class paid more than they would have paid for Xyrem, absent the illegal conduct.

273. Defendants sold Xyrem in Florida, and their conduct had a direct and substantial impact on trade and commerce in Florida. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

Massachusetts Consumer Protection Act ("MCPA")
Mass. Gen. L. Ch. 93A, et seq.

274. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

275. Under the MCPA, "[a]ny person, who has been injured by another person's use or employment of any method, act or practice" that constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

276. As a result of Defendants' illegal agreements, Plaintiff and the Damages Class paid more than they would have paid for Xyrem absent the illegal conduct.

277. Defendants sold Xyrem in Massachusetts, and their conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

Missouri Merchandising Practices Act ("MMPA")
Mo. Rev. Stat. 407.020

278. Under Section 407.020, the MMPA prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. 407.020.

279. The Missouri Attorney General has defined an "unfair practice" as:

> any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive

> decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and
> . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att'y Gen. Reg., 15 CSR 60-8.02.

280. As a result of Defendants' illegal agreement and other unlawful conduct, Plaintiff and the Damages Class paid more than they would have paid for Xyrem, absent the illegal conduct.

281. Defendants sold Xyrem in Missouri, and Defendants' conduct had a direct and substantial impact on trade and commerce in Missouri. Upon information and belief, Defendants also directed advertising and marketing efforts for Xyrem in Missouri. Accordingly, Defendants' conduct falls within the prohibitions in the MMPA.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the proposed Classes, respectfully demands that this Court:

(a) Determines that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and directs that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and declares Plaintiff as a representative of the Classes;

(b) Enters joint and several judgments against the Defendants and in favor of Plaintiff and the Classes;

(c) Grants Plaintiff and the Nationwide Injunction Class equitable relief in the nature of an injunction, disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

(d) Awards the Damages Class damages, trebled, in an amount to be determined at trial;

(e) Awards Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

(f) Awards such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

DATED: June 30, 2020

/s/ Michael J. Freed
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